Exhibit 22

United States of America ex rel. Ven-a-Care of the Florida Keys, Inc. v. Boehringer Ingelheim

Corp. et al.

Civil Action No. 07-10248-PBS

Exhibit to the August 28, 2009 Declaration of James J. Fauci In Opposition To Corrected Boehringer Ingelheim Corporation and Boehringer Ingelheim Pharmaceuticals, Inc.

Local Rule 56.1 Statement of Undisputed Material Facts
in Support of Their Motion For Summary Judgment

$A(0) \oplus A(0) A$ BOEHRINGER INGELHEIM PHARMACEUTICALS, INC. BOARD OF DIRECTORS MEETING OCTORES 1995 Commencement of Meeting 2:00pm 2:00pm to 2:05pm Acceptance of Minutes of the Board of Directors Meeting held on July 6, 1995. 2:05pm to 3:30pm Presentation of latest Preview for 1995 and Budget 1996 for Boehringer Ingelheim Pharmaceuticals, Inc. (Mr. Gerstenberg and Invited Guests: Mr. Berkle and incl. hiplights of men funcción until zono (s. Burle) Mr. Peterson) Update on SunSource relationship. 3:30pm to 3:45pm (Invited Guests: Mr. Lackstrom and Mr. Peterson) Consolidated financial overview of Preview 1995 and 3:45pm to 4:15pm Budget 1996 for BIC and its subsidiaries. (Invited Guest: Mr. Huels) 4:15pm to 4:30pm Legal update on: - R-One/Glaxo v. BIC Litigation - Hexagon Environmental Matter - BIPI Pricing Litigation (Mr. Franks) · Shakpy at Jes treets . Dals for October · Rech mul

Other business

Meeting Adjournment

4:30pm to 4:45pm

4:45pm

ROBERTNGER INGELIEIM PHARMACEUTICALS, INC BOARD OF DIRECTORS MEETING (0)(0)E(0)(8)P(R)(5),(1)(0)P5) TANDAL ORGANISTICS **Section Page** Minutes of the Board of Directors meeting July 6, 1995 1 - 5 I Status of Business - As of August 31, 1995: II • Gross Sales 1 - 6 • Other/Royalty Income 7 • Statement of Income 8 - 11 • Costs for Medical and R&D 12 - 16 Personnel Data 17 - 18

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MINUTES OF THE MEETING OF THE BOARD OF DIRECTORS BOEHRINGER INGELHEIM PHARMACEUTICALS, INC.

JULY 6, 1995

A meeting of the Board of Directors of BOEHRINGER INGELHEIM PHARMACEUTICALS, INC., a Delaware corporation, ("the Corporation"), upon due notice by letter sent to all directors, convened at the offices of the Corporation in Ridgefield, Connecticut at 4:50 p.m. on July 6, 1995.

Board members present were:

Dr. Louis Fernandez, Chairman

Mr. Werner Gerstenberg

Dr. Jere Goyan

Dr. Thomas Heil

Dr. Claus Rohleder

Mr. Gerald C. Wojta

Board members absent:

None

Secretary: Mr. Philip J. Franks

Present by invitation for the entire meeting were:

Mr. Holger Huels

Mr. Walter Poerschmann

Dr. Fernandez presided as Chairman of the meeting. Mr. Franks, the Secretary, took the Minutes.

Dr. Fernandez called the meeting to order at approximately 4:50 p.m. and, it being determined that all directors were present, the meeting was declared open.

Dr. Fernandez then made a motion that the Minutes of the Board meeting of March 3, 1995 be approved. The motion was seconded, and by the unanimous affirmative vote of all directors present, the following resolution was adopted:

RESOLVED that, the Minutes of the Board of Directors meeting held on March 3, 1995 be, and they hereby are, approved in the form submitted to this Board.

Mr. Gerstenberg presented the performance review of BIPI through May 1995 and for the full year using overheads with product details and functional costs as broken down by the P&L format. There were inquiries why PERSANTINE® (dipyridamole) sales were higher than normal and this was explained by Mr. Gerstenberg. He explained further that the Company was expecting self-medication sales of approximately \$32 Million in 1995. Ethical sales are in line with the budget, although the ATROVENT® (ipratropium bromide) Nasal launch will be delayed until August and the COMBIVENT® (albuterol/ipratropium bromide) launch will not take place before the end of the year. The BIPI sales budget for 1995 is \$509,198,000 and the 1995 Preview is \$515,235,000. The operating income budget is \$16,156,000 against a Preview of \$883,000 taking into account additional development costs for TAMSULOSIN® as well as the severance costs for OPINA, elements which could not be foreseen in the budget. The 1995 budget for R&D and Medical expenditures is \$170,396,000. The 1995 Preview is \$175,543,000. One director inquired about the total amount to be spent for TAMSULOSIN® registration, and Mr. Huels replied that the total would be close to \$70 Million.

BIPI personnel costs as a percentage of net sales shows that in 1994 the actual percentage was 29.7%. The 1995 budget was 28.6% and the 1995 Preview was 27.9%.

If one were to exclude R&D and Medical costs, personnel costs for the Company would be 17.9% of net sales.

The Chairman called for other business, and Mr. Gerstenberg suggested that at the next Board meeting the presidents of all BIC subsidiaries be invited to present their budgets directly to the Board.

The Board meetings in 1996 will be held as follows:

March 1, 1996 in Munich, Germany

July 16, 1996 in Ridgefield

October 9, 1996 in Ridgefield

Sneak Preview of BI Worldwide Pharmaceutical Strategy

Dr. Heil made an overhead presentation which outlined the goals for "Project Ethical Pharmaceuticals" which include:

- define "leading" and "world class";
- define critical success factors;
- articulate clear strategic objectives;
- set specific targets for growth and profitability;
- define BI's position in key product market segments; and
- demonstrate implementation of Value Through Innovation in practical business terms.

It is anticipated that by the end of the first half of 1995, the company will begin development of regional strategies based upon worldwide strategies and objectives. The following consultants have been hired to assist in this endeavor:

Mercer Management (for managed care)

Decision Resources (for indications and products)

Coopers & Lybrand (for hospital markets)

The targeted sales in the year 2000 for BI worldwide are 10 Billion DM with 8.5 Billion being from ethical pharmaceuticals and 1.5 Billion from self medications. Consolidated Contribution III will be 45%. Cost of goods should be 20%. Cost of marketing should be 25%. R&D will be 10.5%. Clinical will be 6%. On a region-by-region basis, the sales targets for the year 2000 for the ethical pharmaceutical business are: North and South America, 2.8 Billion DM; Europe, 2.9 Billion DM; and Asia, Africa and Australia, 2.8 Billion DM.

The Consolidated Contribution target for the year 2000 for ethical pharmaceuticals is 38%. In Europe it is presently 28%, in America 38% and in Japan 48%.

The following worldwide objectives are to be met:

- develop management talent further;
- set demanding performance objectives;
- bring new products to market quickly; and
- introduce products on a worldwide basis within two years from first approval.

Dr. Heil stated that the regional strategic objectives for North America are:

- meet OPINA targets and PEP target;
- increase market significance and optimize growth and profitability;

- Page 5
- reduce dependence on ATROVENT®;
- develop responses to managed care;
- solidify generic business;
- define COPD position against generic erosion;
- develop the hospital business (injectables); and
- enter the home care market.

One director inquired as to whether someone is looking into compensation plans and levels to determine if BI will be able to attract the people who can make this happen. Mr. Gerstenberg replied in the affirmative stating that the Corporate Human Resources is very much aware of bringing overall remuneration plans in line with competition.

There ensued a discussion concerning compensation plans and packages at BIC and the lack of stock options which is a very popular kind of incentive compensation in the U.S.A. Mr. Gerstenberg stated that currently the available remuneration packages would allow to a attract good executives from other companies even without stock options being available.

The chairman called for other business and there being none, the meeting was adjourned at 6:10 p.m.

Philip 1 Franks, Secretary

Louis Fernandez, Chairman

Werner Gerstenberg Director

Jere Goyan, Director

Page 5

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Jere Goyan, Director	

MINUTES OF THE BOEHRINGER INGELHEIM PHARMACEUTICALS, INC. BOARD OF DIRECTORS MEETING HELD JULY 6, 1995
Page 6
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Thomas Heil, Director
Claus Rohleder, Director
Gerald C. Wojta, Director

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MINUTES OF THE BOEHRINGER INGELHEIM PHARMACEUTICALS, INC. BOARD OF DIRECTORS MEETING HELD JULY 6, 1995

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Page 6

Thomas Heil, Director

Claus Rohleder, Director

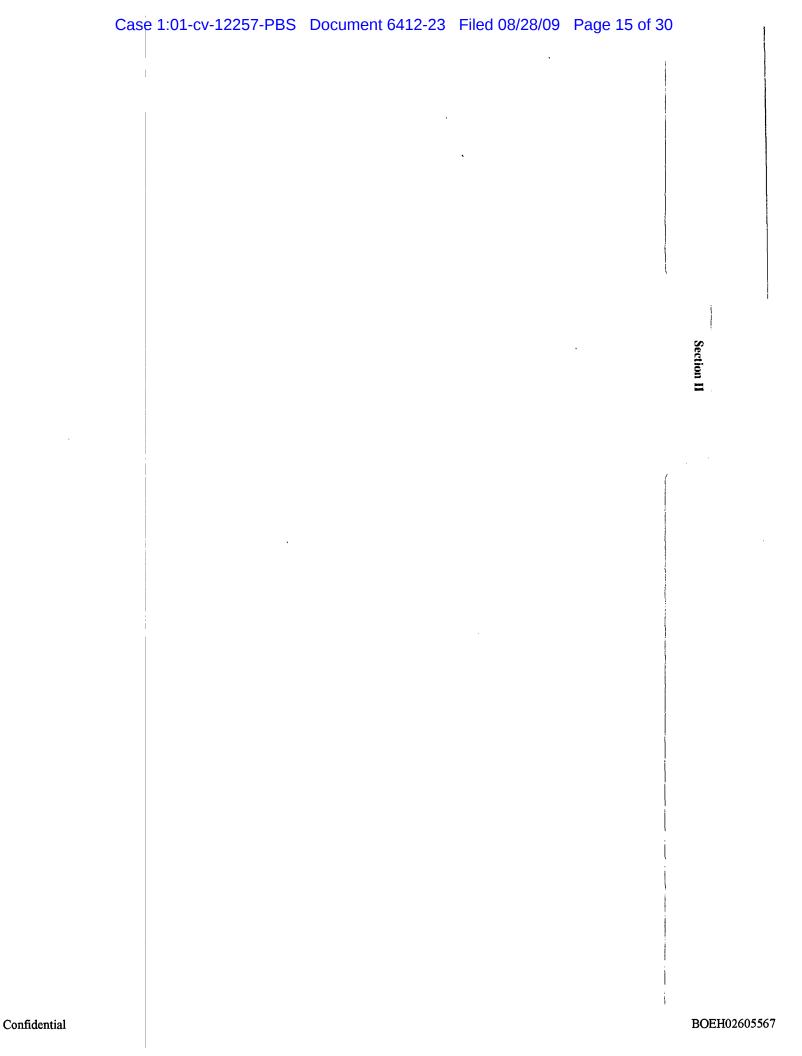
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S OF THE BOEHRINGER INGELHEIM PHARMACEUTICALS, INC. OF DIRECTORS MEETING HELD JULY 6, 1995

Thomas Heil, Director

Claus Rohleder, Director

Gerald C. Wojta, Director



GROSS SALES BY PRODUCT (net of chargebacks)

Thousan	ds	US	\$

Inousand				ec os		inc(Dec)
Actual	Full Year		Expectation	over	Budget	OVEL
August 1995	Eudget 1995		1995	Budget	1996	Expectation
ETHICAL	į		1		1	
10,501	12 000	Catapres	14,792	14%	13,531	-9%
•		Catapres TTS	72,784	-1%	80,000	10%
49,171		Combipres	2,166	-10%	1,831	-15%
1,552		Persantine	17,051	74%	17,500	3%
15,601			29,400	87%	15,331	-48%
24,916	15,720	Mexici	29,700	07.70	10,001	4070
	<u> </u>	Total	1		1	
101 741	114 210	Cardiovascular	136,193	19%	128,193	-6%
101,741	114,213	Caldiovasculai	100,100	. 1070	120,100	- 7,0
			į			
21,316	30 307	Alupent	29,197	-26%	26,802	-8%
183,190		Atrovent MDI	250,000	14%	283,900	14%
	1 .	Atrovent Solution	79,925	24%	112,000	40%
47,785		Atrovent Nasal	13,692	101%	38,300	180%
-		Combivent	15,032	10.70	50,550	
	30,000	Compivent	<u> </u>			
252 204	267 701	Total Pulmonary	372,814	1%	461,002	24%
252,291	307,791	Total Fullionary	372,014	.,,,	401,002	2770
	}	Nevirapine		_	8,388	-
10,962	15 500	Other Ethical	15,347	-2%	13,080	-15%
•		Generics - RLI	2,063		2,370	15%
1,659	1 '		2,000	-2070	286	
000 074		Other Ethical Gross Sales	526,417	5%	613,319	17%
366,653	501,073	Less:	020,411	 	0.10,0.0	
0.075	0.053	Discounts & Returns	10,353	4%	12,129	17%
9,972	9,952	Medicaid & Other	10,555	1	12,.20	
07.057	24 500	Rebates	40,086	16%	54,358	36%
27,857	34,500	Repates	40,000	1 10%	04,000	
	 -	Net Sales		 		
220 00	456,623	3	475,978	4%	546,832	15%
328,824	450,023	Royalty &	475,570	1 - 7/0	040,002	
2 963	6,584		6,584	0%	11,896	81%
2,863	0,304	Other income	0,004	1	,000	
224 607	462 207	Net Sales - Ethical	482,562	4%	558,728	16%
331,687	403,207	Net Sales - Eulical	402,002	7,0		
(OE) = 000	DIOATION.			T		Γ
	DICATION:	Net Sales of Goods	39,896	-9%	55,859	40%
23,940			2,014			
1,386	2,014	Royalty & Other Income Total Net Sales - Self	2,014	1	2,004	
		•	41,910	-9%	58,193	39%
25,320	45,991	Medication	41,310	-3/6	00,100	
·		Terran National		7	1	
		Total Net Sales -	E04 470	3%	616,921	18%
357,013	3 509,198	Company	524,472	3%	010,921	10%

B. I. PHARMACEUTICALS, INC. 1996 BUDGET

ETHICAL GROSS SALES

Ethical Products - Overview

Health Care Reform

Health care reform continues to be a political subject in the USA, but the heat has gone out of the debate. The Clinton Administration approach and the Democratic party reforms are dead. The Republican controlled Congress is pursuing reform driven by financial concerns to help reduce the Federal deficit rather than any need to improve the system. A number of proposals are currently being considered and there is no doubt some reform will be instituted.

During 1996 and beyond, it is expected that the trend toward managed care will continue, with a corresponding decrease in the number of "fee-for-service" and cash paying patients. The trend will be accentuated by employers "encouraging" their employees to join managed care health plans and by government efforts to persuade Medicare patients to join similar plans.

The result for the pharmaceutical industry will be a steady increase in the percentage of sales that are ultimately controlled by a contract with price rebates/discounts. It is expected that BIPI will pay out in excess of \$40M and \$50M in public and private rebate payments in 1995 and 1996 respectively.

Current Business

For 1996, the greatest opportunities for the BIPI R_x business is with developing Atrovent Nasal Spray sales and maximizing Atrovent MDI sales. The greatest threat to the business in the future is the introduction of a generic ipratropium aerosol. Since it is possible that generic ipratropium could be launched in the first quarter 1997, BIPI has pre-empted this possibility through its planned launch of a generic by RLI prior to another generic's entry into the market.

Ethical Products

The 1996 Budget for ethical Sales is based on the following assumptions.

- Atrovent Nasal Spray will be launched in October of 1995.
- No generic ipratropium aerosols will be introduced in 1996.
- Combivent Inhalation Aerosol (MDI) will not be introduced in 1996. (See discussion under MEDICAL.)
- Atrovent Solution will lose its status as a "single source" product in September, 1996. RLI will launch a generic in July, prior to other generics entering the market in October.
- Nevirapine will be launched by the RLI sales organization in July 1996. Sales, Cost of Goods, Promotion Expense, Distribution, Clinical, and other products costs will be included within BIPI.
- Generic competition for Mexitil will increase.

Key Ethical Products

Millions (M)	Expectation 1995	Budget 1996	% Increase
Atrovent MDI	250.0	283.9	14%
Atrovent Solution	79.9	112.0	40%
Catapres-TTS	72.8	80.0	10%
Atrovent Nasal	<u>13.7</u>	<u>38.3</u>	180%
Sub-Total	<u>416.4</u>	<u>514.2</u>	
% of Total			
Ethical Gross Sales	<u>79%</u>	<u>84%</u>	

All Amounts in Millions of U.S.\$

Ethical Products (continued)

Atrovent MDI will continue to grow, and represents 46% of total sales in 1996. The release of the American Thoracic Society treatment guidelines on COPD, in which Atrovent is favorably positioned, will positively influence sales in the same way the New England Journal of Medicine review did in 1993-1994. Atrovent MDI will lay the foundation for Combivent MDI -- which will be launched in early 1997. To achieve the sales objective, 35% of field effort and 45% of Direct Promotion expenditure will be devoted to Atrovent MDI.

Atrovent Solution, even though it will lose exclusivity in September, will be the second largest, single product in the range with 18% of sales. These sales will be achieved with limited promotion. Combined, the solution and MDI product will account for 64% of the Company's sales in 1996.

Catapres-TTS sales growth of 10% in 1996 will be generated by dedicating 25% of the total field force effort and continued promotional expenditures for samples and other forms of direct promotion. These figures reflect the careful targeting of current and potential prescribers of the product.

Atrovent Nasal Spray, assuming it is launched in October 1995, will contribute 6.35% of sales in 1996. The product will be promoted solely by BIPI.

No other product forecast contributes more than 5% of sales in 1996.

Ethical Products (continued)

Other Product Sales

Mexitil will contribute 5.6% of total sales in 1995. Due to the <u>lack</u> of multiple generics following the patent expiration in May 1995, sales in 1995 will be much higher than originally budgeted. Assuming generic erosion in 1996, sales are forecast at \$15.3M or 2.5% of sales.

It does appear that the generic erosion rate for multi-source products (*Catapres*, *Alupent* Solution/Tablets, *Persantine*) may be slowing down. This is somewhat surprising in view of the very active generic substitution campaigns undertaken by retail pharmacists, PBMs, and HMOs.

While the rate of decline may have slowed, there is, nonetheless, still a decline. In 1996, products that will have generic competition for the whole year will contribute less than 10% of total forecast sales. No promotion will be undertaken for these products, e.g., Catapres tablets, Combipres, Alupent Tablets, Syrup, Inhalant Solution, Persantine, Resphid and Mexitil.

Serentil will continue with the same level in forecast sales. An in-depth review of a possible co-promotion arrangement with Scios-Nova concluded that the sales increase obtained from such an arrangement would not be sufficient to justify co-promotion.

Nevirapine is on an FDA fast track review. This would allow temporary approval of the product while final studies are performed. NDA submissions will be at the end of 1995, with anticipated temporary approval for launch in July.

OPINA COMPARISON

The Budget 1996 Ethical Net Sales of \$536.5M are 136% of the 1996 OPINA target of \$395.0M.

B.I. PHARMACEUTICALS, INC. 1996 BUDGET

SELF MEDICATION

When BIPI assumed marketing responsibility for Ginsana® in January 1995, factory sales had declined to a steady rate of \$2 million per month versus the \$3.3 million monthly level originally budgeted for 1995 based on SunSource expectations. By June-July-August 1995, sales had increased to the \$3 million monthly level, through a 60-count bonus pack promotion, new retail distribution of the larger size, and an improved advertising program. Ginsana® sales are expected to end the year at \$32 million. The launch of Ginkoba™, a licensed ginkgo biloba capsule, will add at least \$2.5 million in sales, and seems likely to exceed that figure.

Pharmaton sales in 1996 include sales for Ginsana® (\$38.4M) and Ginkoba™ (\$13.3M). Ginsana® sales will benefit from a dedicated field force and the switch from radio to TV advertising. Ginkoba™ sales (launched in 1995) reflect the remainder of the pipeline stocking, along with our anticipated sales base for the product. Also included are sales to Ciba-Geigy for Dulcolax® of \$5.2M. In 1996, we will have discontinued the manufacture and sale of Nostril of Ciba-Geigy as BIPI released the production rights to Ciba Consumer Products, allowing them to purchase their requirements from other sources.

Standard Cost of Sales is \$4.3M above the 1995 Expectation due to a sales volume increase, partially offset by lower unit costs. Favorable rate variances are the result of lower operating cost of the BIPI Production facility. The 1995 Expectation and the 1996 Budget reflect the free Ginsana® capsules (package includes 60 for the price of 50) that Pharmaton has agreed to provide BIPI.

In 1995, distribution, commissions and consulting fees are paid to SunSource in compensation for their part in selling the Pharmaton products. In 1996, the total responsibility for sales and distribution shift to BIPI. We will add our own sales force and marketing and advertising will be increased significantly. Additional spending in Consumer Media and Consumer Promotion is needed to advance sales in the marketplace. The Media increase is mostly in support of the shift from radio to TV advertising. In addition, the cost of Towne-Oller audit data for market research has been added to the budget. This had previously been paid for by SunSource.

Recent consumer research indicates that the high price of Ginsana® may be inhibiting sales. In the short-term, added on-pack rebate and coupon offers will help; further analysis will determine whether additional measures (including price reduction) are necessary.

The potential purchase of the SunSource products, Rejuvex and Garlique, are not included in this budget. Anticipated sales of these products are \$20.0M, with a \$3.7M Contribution IA.

OTHER / ROYALTY INCOME

Thousands US \$

Augus Budget	11995		Budget 1995	Expectation 1995	Budget 1996
SS.codoodoot SoobiiS	232444444		22222222222		SS 55 A A A A A A A A A A A A A A A A A
ETHICAL					
		OTHER INCOME:			
•	-	Monopril	2,185	2,185	1,748
4.450	000	Third Party	4 047	400	0.504
1,159	628	Contract	1,617	493	3,594
		TOTAL OTHER		•	
1,159	628	INCOME	3,802	2,678	5,342
1,100			5,002		<u> </u>
\		ROYALTY:			
1,667	2,116	Persantine I V - DuPont	2,500	3,088	2,750
188	119	Combivent	282	282	282
-	-	Generics - RLI	-	440	3,522
•	•	Other		96	-
4 055	0.005	TOTAL ROYALTY	0.700	9.000	0.554
1,855	2,235	INCOME	2,782	3,906	6,554
3,014	2,863	TOTAL ETHICAL	6,584	6,584	11,896

SELF MED	CATION	 <u>\:</u>			
1,265		ROYALTY & OTHER: Dulcolax - Ciba-Geigy	2,014	2,014	2,334

1070 1010	TOTAL COMPANY	0 500	8.598 14.230
4,279 4,249 7	INIAI COMPANY	1 8.598 1	8.598 14.230
7,410 7,470 1		1 0,000 1	0,000 17,200

COMMENTS:

Other income includes residual payments from the Monopril co-promotion. Third Party work is for MGI, TIMERX and Interneuron Pharmaceuticals Inc. (IPI). IPI's product, Dexfenfluramine, will generate \$2.9M of revenue in 1996. In total, third party work has a net contribution of 23%.

Royalty income from DuPont and Ciba-Geigy continues to be generated from the sales of Persantine IV and Dulcolax. Combivent (sold internationally by B.I.) and generics sold by RLI are all revenues from B.I. affiliated companies.

STATEMENT OF INCOME

(Presentation Basis - FSII/German GAAP)

Thousands U.S.\$

	Augus Budget	t 1995 Actual		Budget 1995	Expectation 1995	Budget 1996
å	8					
L	330,060	357,013	Net Sales	509,198	524,472	616,921
	72,126	76,492	Standard Cost of Goods Sold *	110,308	115,678	132,050
-	33,796	37,885	Royalties	51,205	55,070	65,034
Į	80,604	63,820	Marketing & Advertising	117,817	106,635	135,542
١	•	-	R & D - National	-	840	1,463
-	3,755	4,248	Medical - National	6,279	7,428	7,029
ı	12,351	11,309	Administration	18,538	17,556	17,279
ı	10,107	9,917	Distribution	15,159	16,723	16,178
L	6,325	10,606	Other	9,620	9,887	14,369
	110,996	142,736	Contribution III	180,272	194,655	227,977
- 1	38,019	43,013	Medical - International	62,716	74,290	70,660
1	67,367	59,585	Research & Development	101,401	94,831	103,052
-	_	12,000	Other - International		29,100	350
	5,610	28,138	Operating Income (Loss)	16,155	(3,566)	53,915
	(3,910)	(3,238)	Financial Income (Expense)	(5,865)	(2,623)	10,503 50,000
ŀ			Holding Income (Expense)	-	-	50,000
	1,700	24,900	Profit (Loss) Before Tax	10,290	(6,189)	114,418
	5,875	2,142	Income Tax	8,812	6,051	21,000
	(4,175)	22,758	Net income (Loss) After Tax	1,478	(12,240)	93,418

^{*} Adjusted for effects of Section 936 pricing. Section 936 pricing restated to 1992 levels. The net effect is additional income of \$891 in the 1995 Expectation

B. I. PHARMACEUTICALS, INC. INCOME STATEMENT

COST OF SALES

Standard Cost of Sales

Ethical Standard Cost of Sales as a percentage of net sales is 20.2% in 1995 and 19.6% in the 1996 Budget. Production cost is projected to decline 3.4% from the 1995 Expectation as a result of reduced operating costs now below 1995 levels in the areas of headcount and support services. The purchase price of aerosols in 1996 will be below 1995 prices based on the current supply agreement that has been negotiated between BIPI and 3M. The annual estimated reduction in aerosol cost is \$2.0M. BIPI and Sandoz have reached an agreement that will double the cost of Serentil in order to maintain a steady supply of the product, adding \$1.3M to the Cost of Sales. Contribution I of Serentil will be at 68%.

SALES AND MARKETING - ETHICAL

Overall, Sales and Marketing expenditures will total \$110.0M or 17.9% of Gross Sales in 1996.

Direct Promotion

The focus of spending will be on our top products which comprise 83% of the Direct Promotion budget. The key product will be Atrovent MDI, with spending of \$15.2M. In 1996, we will initiate a COPD awareness promotion at a cost of \$5.4M. The goal is to optimize sales and expand the COPD market which will be the foundation for Combivent sales. The Combivent launch is expected in early 1997, and promotional spending will be \$1.8M. Due to the recent launch, Atrovent Nasal promotional spending will increase 75% to \$13.0M. Catapres-TTS will be supported by \$4.1M in direct promotion.

The promotional spending will be divided between several categories, the more significant of which will be samples (\$12.2M) and journal advertising space (\$8.1M). Other promotion will be associated with Nevirapine for an Indigent Patient Program (free goods) (\$1.7M), and Tamsulosin for the Phase IIIB/IV trials (\$1.7M).

SALES AND MARKETING - ETHICAL (continued)

General Promotion and Field Force

General Promotion and Field Force will increase 7.7% (\$5.0M) over Expectation 1995. Of this increase, Personnel Cost represents \$1.8M. This is a combination of merit increases and the filling of several positions open from 1995. Other significant increases are in the travel-related and training areas for the roll-out of the new ETMS System scheduled for the second half of 1996. The new system will require training of the field force on both Windows and ETMS. Outside Services reflects an increase over Expectation due to the costs associated with Drug Distribution Data. This cost is partially driven by sales volume and sales of the promoted products have increased by 21.4%. Marketing will also begin receiving data on the therapeutic class associated with Atrovent Nasal. Requested services have also increased by \$1.6M, mainly from space and warehouse storage charges, along with increased projects with I.S.

IDLE PLANT, VARIANCES, AND OTHER INCOME/EXPENSE

The 1996 Budget Cost of Idle Capacity represents \$2.0M in under-utilization of the production equipment in the Plant. In addition, the Cost of Idle Capacity represents \$.4M in OPINA-related cost.

The 1996 Budget incorporates the 1995 Expectation variances in the standard unit cost. The 1996 planned variance of \$1.7M represents \$.9M in adjustments to the expense budgets and \$.8M in the delivery price for the Nevirapine active ingredients which were identified after the standard cost was finalized.

Included in Other Income/Expense are costs associated with general litigation reserves, loss on disposal of fixed assets, inventory write-offs, and revaluations. New in 1996 is the anticipated \$2.0M milestone payment to Yamanouchi which will coincide with the Tamsulosin NDA filing.

OTHER INCOME/EXPENSE - INTERNATIONAL

Included in the 1995 Expectation are costs associated with OPINA and Sunsource agreement changes. The \$15.9M separation and related costs and an additional \$10.0M depreciation charge for the excess plant capacity after 1999 are related to the OPINA Project. The discontinuance of Sunsource as our distribution agent and subsequent termination agreement has led to a \$3.2M charge. This expense was a negotiated settlement based upon 1995 sales performance of our Pharmaton products.

FINANCIAL INCOME

The Financial Income results from the positive cash balance derived from the \$200+M equity infusion from BIC.

HOLDING INCOME

A final dividend of \$50.0M is projected from Bilchem Ltd. as a result of the company shutdown.

INCOME TAXES

Income Taxes reflect a 10% Puerto Rico tollgate tax of \$5.0M, projected state income tax of \$4.0M, and Federal Income Tax of \$12.0M. The Federal Income Tax is based upon a regular tax rate of 35%, reduced by a Research Tax Credit down to a 20% effective tax level.

STATEMENT OF INCOME - Self Medication

Thousands U.S.\$

Thousands U.	J. 				
August Budget	1995 Actual		Budget 1995	Expectation 1995	Budget 1996
26,665	20,419	Pharmaton	40,000	34,522	51,650
3,199	3,521	Ciba-Geigy	4,777	5,719	5,242
29,864	23,940	Gross Sales - SM	44,777	40,241	56,892
33	23	Less: Discounts	800	345	1,033
29,831	23,917	Net Sales of Goods	43,977	39,896	55,859
1,265	1,386	Royalty Income	2,014	2,014	2,334
31,096	25,303	Total Net Sales - Self Medication	45,991	41,910	58,193
14,951	12,202	Cost of Goods Sold	22,836	20,289	24,634
1,151	1,246	Royalties	1,726	1,726	2,122
9,254	6,216	Marketing & Advertising	13,881	14,342	26,702
3,270	2,732	Distribution	4,800	4,465	2,658
13	1,336	Other	(20)	(189)	-
2,457	1,571	Contribution III	2,768	1,277	2,077

B. I. PHARMACEUTICALS, INC. COSTS FOR R&D AND MEDICAL

Thousands US \$

Augus	st 95		Budget	Expectation	Budg
300 get	Acqual		1995	1995	1996
		National Expense	1	[
<u>-</u>	•	R & D Costs	_	840	1,
3,755	4,248	Medical	6,279	7,428	7,0
3,755	4,248	Total - National	6,279	8,268	8,4
		International Expenses			
38,019	43,013	Medical	62,716	74,290	70,
58,299	51,656	R & D Costs	88,401	81,831	89,
9,068	7,929	R & D Bio - Mega @ 80%	13,000	13,000	13,
105,386	102,598	Total Intrn'i Expenses	164,117	169,121	173,
100 444	400 040	TOTAL MEDICAL &	170 202	177 290	192
109,141	106,846	R & D COSTS	170,396	177,389	182,
33.07%	29.93%	As a % of Net Sales	33.46%	33.82%	29.

MEDICAL AND R&D

MEDICAL/DRUG REGULATORY AFFAIRS

The 1996 Medical/Drug Regulatory Affairs budget totals \$77.7M. The changes from the 1995 Expectation to the 1996 Budget reflect increased costs associated with the rise in the number of active centers and patients planned for 1996 (9,922 patients) as compared to 1995 (5,175 patients). Also, the number of IND and NDA's being planned for 1996 doubles the activity of 1995. For comparison, it is important to look at the Expectation, net of Tamsulosin, or \$70.7M. The \$11.0M currently anticipated for Phase III development expense for the Tamsulosin project with Yamanouchi was not budgeted in 1995.

Some of the major programs being supported are Telmisartan, Cerestat, Tiotropium, Atrovent Nasal (including .12% in Perennial Rhinitis), as well as the Enlimomab and Viramune programs. We are also scheduling resources and grants for the BIBU, BIMT17, and DAU programs.

In addition to these and other ongoing projects, costs have been included for the compilation of existing international substance databases for Atrovent and Combivent. These databases will be used to provide quick access to answer unexpected safety questions. In addition, there are CRO costs for the continued maintenance of the Tamsulosin database.

The 1996 Budget was prepared based upon the assumption that projects would be conducted as planned. It should be noted that no costs have been budgeted in 1996 for the Tamsulosin license agreement or Bisolvon clinical supplies.